REMARKS

Claims 2 and 3 were previously cancelled. Claims 4-10 were previously withdrawn. Applicants reserve the right to file continuation or divisional applications directed to the cancelled and withdrawn subject matter. Claim 1 is currently under consideration.

Rejection Under 35 U.S.C. §112, First Paragraph

Claim 1 is rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner states that the claim encompasses a method for the treatment of glomerular nephritis wherein streptococcus is not the causative agent and such method lacks support in the originally filed specification. The Examiner then concludes that the previous amendments to claim 1 constitute new matter. See Office Action page 2.

35 U.S.C. §112, first paragraph requires that a specification enable one skilled in the art to make and use the claimed invention. A specification fails to meet this requirement if the specification fails to provide sufficient information regarding the claimed subject matter to enable a skilled artisan to make and use the claimed invention. "However, to comply with 35 U.S.C. §112, first paragraph, it is not necessary to 'enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.' CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003)." (MPEP §2164). To determine if sufficient information is provided, one must inquire whether the claimed invention can be practiced without undue experimentation.
MPEP §2164.01. That some experimentation may be required is not fatal because the issue is whether the experimentation is undue. In re Vaeck, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

Applicants respectfully traverse the rejection and assert that the claims are fully enabled. Although streptococcal infection is not the only causative agent of glomerular nephritis, it is considered to be the most common cause. The development of glomerular nephritis takes place subsequent to the infection itself. As a result, indications that an infection had previously taken place may not always be apparent. Therefore, the present method may be used as a treatment for glomerular nephritis in general, without a requirement of knowledge of a previous streptococci

infection. The effectiveness of the treatment may be dependent upon the actual physical cause. Applicants also respectfully assert that although induction of autoimmune responses is a pathological effect derived from the immune response to the infectious agent, a pathological effect involving an immune response may be achieved in other ways. For example, glomerular nephritis is not an autoimmune disease. After a streptococcal infection, the pathological condition termed glomerular nephritis can be caused by an accumulation of immune complexes (antigen/antibody) that become trapped in the glomeruli. This is in essence a physical defect derived from blockage. No evidence has been found that damage to kidneys caused by an autoimmune response generated against kidney protein antigens is part of the development of glomerular nephritis. Instead, the original streptococcal antigens generate the pathology. Therefore, the methods of the present invention would be beneficial to a subject by reducing an antibody response by these antigens.

Applicants also contend that the previous amendments to the claims do not constitute "new matter." Applicants respectfully refer the Examiner's attention to page 32, lines 32-28 of the specification as filed, which reads as follows:

> In this process a reagent or a combination of reagents capable of producing selective immune down regulation and comprising a fragment or fragments thereof of such infectious agent is introduced into the subject, thereby establishing immune down regulation in the subject. A preferred infectious bacterial agent for use in this process is streptococcus, including particularly the forms of streptococcus that cause rheumatic fever or glomerular nephritis.

The specification clearly discusses the nature of the **reagent** as being from streptococcus, but there is no statement to the effect that glomerular nephritis in a subject must in itself be known to be caused by streptococcal infection. In addition, originally filed claim 3 recites that the source of the **reagent** is the streptococcus, the causative agent for glomerular nephritis.

In addition, the specification identifies a host of unwanted immune responses on page 1, lines 18-23. Included in this listing are "immune complex-based destruction of certain tissues" in addition to "autoimmune disease." As explained previously, these terms provide a more appropriate description of the development of glomerular nephritis after a streptococcal infection.

Claim 1 recites a method for inducing SIDR to glomerular nephritis comprising administering components or fragments of streptococcus bacteria. This process is clearly described in the specification and does not constitute new matter, as described above. One of skill in the art would thus conclude that Applicants were in possession of the claimed subject matter. Claim 1 therefore satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal the rejection.

Rejection Under 35 U.S.C. §103(a)

Claim 1 is rejected under 35 U.S.C. §103(a) as unpatentable over Chen *et al.*, (WO 96/39176; hereinafter "Chen") in view of Katz (US Patent No. 4,950,469). The Office Action states:

> Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen. (see claims 1-13, pages 12-14, 40, 41). Oral tolerance is a form of "selective immune down regulation (see specification, page 17, second paragraph). Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved in the pathogenesis of rheumatic fever. Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues (see column 6, first). Katz teaches that agents which prevent binding of said antibodies could be used to treat rheumatic fever (see column 6, first paragraph).

Office Action pages 3-4. In response to Applicants' previously submitted arguments, the Examiner states: (1) Chen defines the term "autoantigen" to include Applicants' presently claimed process; (2) the streptococcal antigen disclosed by Katz constitutes an autoantigen as defined by Chen; and (3) Katz teaches that rheumatic fever involves an autoimmune response caused by anti-streptococcal antibodies. Office Action pages 4-7.

Applicants respectfully traverse the rejection and contend the combination of Chen in view of Katz does not render claim 1 obvious. The Examiner cites to page 8, lines 18-20 of Chen as defining the term autoantigen: "The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease **when administered to a**

mammals." (Emphasis added). As explained fully in Applicants' previously submitted Response, there was no description of the administration of streptococcal antigens that induce autoimmune conditions until the Quinn paper was published in 2001. As such, it was not known that streptococcal antigens would induce a condition similar to rheumatic fever at the time of the filing and thereby fulfill the definition of Chen. Thus, at the time of the Chen filing there was no evidence in the literature that streptococcal fragments or lysates alone can induce an autoimmune response in a test subject. Although the Chen reference describes the use of oral tolerization to reduce antibody production, this method is used strictly for the purpose of ameliorating autoimmune response. No hint or suggestion is given for a utility in providing benefits by reducing a disease caused by a physical accumulation of antigen/antibody complexes derived from a streptococcal infection.

Thus, contrary to the Examiner's contentions, there was no evidence in the literature that streptococcal fragments or lysates alone can induce an autoimmune response. Thus, one of skill in the art would have no motivation to combine the teachings of Chen and Katz because it was not known that the currently claimed streptococcal fragments or lysates would produce the required response. One would have no expectation that the combination would be effective because, contrary to the Examiners contentions, there was no indication at the time of filing that the streptococcal antigen disclosed by Katz would function as an autoantigen as defined by Chen. Claim 1 is not anticipated by the combination of Chen and Katz. Withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit that all claims are in condition for allowance. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel at the number listed below to resolve such issues and place all claims in condition for allowance.

The Examiner is invited to contact the undersigned at 412-918-1100 to discuss any matter concerning this application.

The Office is hereby authorized to charge any additional fees or credit any overpayments under 37 C.F.R. § 1.16 or § 1.17 to the deposit account number 50-0525.

Respectfully submitted,

METZ LEWIS LLC

By: __/Kellie L. Carden/_____

Kellie L. Carden
Registration No. 52,696

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Metz Lewis LLC
11 Stanwix Street
18th Floor
Pittsburgh, PA 15222
(412) 918-1100